

In The Claims:

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Claim 1. (currently amended) A biopolymer marker [selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4 or at least one analyte thereof useful in indicating at least one particular disease state] peptide consisting of amino acid residues 2-11 of SEQ ID NO:1 diagnostic for Type II diabetes.

Claims 2-38. (currently canceled).

Claim 39. (new) A method for diagnosing Type II diabetes comprising:

(a) obtaining a sample from a patient;

(b) conducting mass spectrometric analysis on said sample in a manner effective to maximize elucidation of discernible peptide fragments contained therein; and

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(c) comparing mass spectrum profiles of a peptide consisting of amino acid residues 2-11 of SEQ ID NO:1 to mass spectrum profiles of peptides elucidated from said sample; wherein recognition of a mass spectrum profile in the sample displaying the characteristic profile of the mass spectrum profile for the peptide consisting of amino acid residues 2-11 of SEQ ID NO:1 is diagnostic for Type II diabetes.

Claim 40. (new) The method of claim 39, wherein the sample is an unfractionated body fluid or a tissue sample.

Claim 41. (new) The method of claim 39, wherein said sample is selected from the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

Claim 42. (new) The method of claim 39, wherein said mass spectrometric analysis is selected from the group consisting of Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS, TOF-TOF, ESI-Q-TOF and ION-TRAP.

Claim 43. (new) The method of claim 39, wherein said patient is a human.

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Claim 44. (new) A Type II diabetes diagnostic kit comprising:  
(a) a peptide consisting of amino acid residues 2-11 of SEQ ID NO:1 and (b) an antibody that binds to said peptide in a sample from a patient.

Claim 45. (new) The diagnostic assay kit of claim 44, wherein said antibody is immobilized on a solid support.

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Claim 46. (new) The diagnostic kit of claim 44, wherein said antibody is labeled.

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## Restriction

Restriction to one of the following inventions has been required under 35 USC 121:

I. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:1, classified in class 530, subclass 300.

II. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:2, classified in class 530, subclass 300.

III. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:3, classified in class 530, subclass 300.

IV. Claims 1-2, drawn to a biopolymer marker, comprising SEQ ID NO:4, classified in class 530, subclass 300.

V. Claims 3-9, drawn to a method for categorizing a disease state, classified in class 424, subclass 93.1.

VI. Claims 10-28, drawn to a diagnostic assay kit, classified in 436, subclass 808. **(please elect one SEQ ID number to be searched)**

VII. Claims 29-32, drawn to polyclonal antibodies, classified in Class 436, subclass 547. **(please elect one SEQ ID number to be searched)**

VIII. Claims 33-37, drawn to a method for identifying a therapeutic process related to a disease state, classified in class 436, subclass 517. **(please elect one SEQ ID number to be searched)**

IX. Claim 38, drawn to a method for regulating a disease state, classified in class 435, subclass 7.1. (please elect one SEQ ID number to be searched)

### Election and Request For Rejoining Claims

Applicants here elect without traverse Group I (claims 1 and 2, as drawn to a biopolymer marker comprising SEQ ID NO:1) for prosecution on the merits.

Applicants respectfully request that the Examiner consider rejoining claims 39-46 under *Ochiai* after the claims of the elected invention (Group I) are found allowable. The instant application is related in claim format to several pending applications of which serial number 09/846,352 is exemplary. The biopolymer marker of serial number 09/846,352 was found to be novel and subsequently claims reading on methods and kits limited to its use were rejoined with the claims reading on the biopolymer marker under *Ochiai*. Similarly, if the peptide consisting of amino acid residues 2-11 of SEQ ID NO:1 of the instant application is found to be novel, methods and kits limited to its use should also be novel. Thus, in an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner enter the new claims (39-46) added herein by amendment and consider rejoining them with claims reading on the biopolymer marker consisting of amino acid residues 2-11 of SEQ ID NO:1 when such claims are found allowable.

### Claim Status/Support For Amendments

Claim 1 has been amended. Claims 2-38 have been canceled. Claims 39-46 have been added. Claims 1 and 39-46 are pending in the instant application.

No new matter has been added by the amendments to the specification.

The title of the application has been amended to more clearly indicate the invention to which the pending claims are drawn.

Several protocols in the experimental section of the detailed description have been amended to properly identify the trademark SEPHAROSE.

The abstract has been amended to remove the legal phraseology ("said").

No new matter has been added by the addition of new claims 39-46. The subject matter of new claims 39-46 corresponds to subject matter originally found in canceled claims 2-38. The above additions to the claims also find basis in the original disclosure at page 25, line 16 to page 26, line 22. The method of new claim 39 is described in detail at pages 37-47. Page 47, line 21 to page 48, line 2 refers to use of various types of samples and page 38, lines 20-23, refers to different mass spectrometric techniques which can be used in the methods of the instant invention. Page 46, line 21 refers to practicing the claimed methods with a human

patient. Pages 47-48 describe kits contemplated for use with the claimed methods. Page 47, lines 19-20, refers particularly to the immobilizing on solid supports and labeling of components of the contemplated kits. It is clear from these specific recitations and from the description of methods utilized that the methods and types of kits recited in the newly added claims (39-46) were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

#### Sequence compliance

The first (K) and last (Q) amino acid residues of SEQ ID NO:1 are shown in parentheses in the original disclosure at page 46, line 6 (as are the first and last amino acid residues of non-elected SEQ ID NOS:2-4). When carrying out mass spectrometric procedures, it is possible to fragment a whole molecule, depending upon the enzyme used for digestion. A sequence is often predicted from these fragments but often the sequence is not identified completely. It is conventional in the art to show the missing portions of the predicted sequence in parentheses. The first and last amino acid residues of SEQ ID NO:1 are predicted residues as disclosed by the use of parentheses. The first and last amino acid residues of SEQ ID NO:1 are disclosed in the specification and the Sequence Listing, however the biopolymer marker peptide identified in patient sera consists of amino acid residues 2-11 of SEQ ID



NO:1. The amendments made herein to the claims and specification limiting the marker sequences to specific amino acid residues are made for the purpose of clarification of the use of parentheses only. The claims as amended limit the biopolymer marker peptide sequence to amino acid residues 2-11 of SEQ ID NO:1.